

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION

IN RE: GARDASIL PRODUCTS  
LIABILITY LITIGATION

DOCKET NO. 3:22-MD-03036

TRANSCRIPT OF PRETRIAL CONFERENCE  
BEFORE THE HONORABLE ROBERT J. CONRAD, JR.  
UNITED STATES DISTRICT COURT JUDGE  
WEDNESDAY, DECEMBER 14, 2022 AT 11 A.M.

APPEARANCES:

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and

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1 THE COURT: Good morning, everyone.

2 ALL: Good morning.

3 THE COURT: All right. We're here in the Gardasil  
4 MDL for a second pretrial conference. And I would ask the  
5 lawyers, for the record, to introduce themselves and tell me  
6 who you're representing, the lawyers who are going to have  
7 some active role in this hearing.

8 MR. PENNOCK: Good morning, Your Honor. Paul  
9 Pennock for plaintiffs.

10 THE COURT: Good morning.

11 MS. MULLINS: Good morning, Your Honor. Your  
12 Honor, I'm Allison Mullins also for the plaintiffs.

13 MS. LANIER: Good morning, Your Honor. Rachel  
14 Lanier, also for the plaintiffs.

15 MR. DOWNING: Good morning, Your Honor. Andrew  
16 Downing also for the plaintiffs.

17 MR. ESFANDIARI: And good morning, Your Honor.  
18 Bijan Esfandiari, also on behalf of the plaintiffs.

19 THE COURT: Welcome to all of you.  
20 And do we have anybody participating virtually?

21 MR. ESFANDIARI: Not at today's hearing, Your  
22 Honor, just observing.

23 THE COURT: Thank you.

24 And for the defendants.

25 MR. WRIGHT: Good morning, Your Honor. David

1 Wright on behalf of the defendants.

2 MS. JULIEN: Good morning, your Honor. Allyson  
3 Julien for Merck.

4 MR. DUKES: Good morning, Your Honor. David Dukes  
5 for Merck.

6 THE COURT: Good morning to all of you, as well.

7 I want to thank you for working hard on this case  
8 between the last hearing and this. It seems to me that you  
9 all have done a superb job of agreeing to the things that  
10 you can agree to and teeing things up for me that need to be  
11 resolved by the Court. That's the way this thing is  
12 supposed to work. And when it does work this way, it's a  
13 pleasure to be part of.

14 I'm going to take some things up in the order that  
15 I approach them and may be somewhat different than the order  
16 of the suggested agenda, but I think that we'll cover all  
17 the matters on the suggested agenda; and if not, be happy to  
18 hear from you when we're through with it.

19 The first thing I would like to address is on the  
20 plaintiff's side, and that is the recommendations for  
21 additional involvement on committees by various lawyers.

22 And so we have a -- we have previously appointed  
23 liaison and counsel. And there's a proposal for an  
24 executive committee, a steering committee, a federal state  
25 court liaison. And I'd like to know more about that and why

1 you feel it's necessary and how it impacts the cost of the  
2 litigation and the effectiveness of the litigation and a  
3 little bit more about why we need so many lawyers on so many  
4 different committees.

5 I don't know who wants to run with that.  
6 Mr. Pennock, you're free to.

7 MR. PENNOCK: Thank you, Your Honor.

8 We have been working with a number of lawyers as a  
9 team. And there certainly is a core group, which Your  
10 Honor, we're grateful, appointed to -- as the top of the  
11 leadership.

12 But as is, I think, typical, we need a fulsome  
13 team to pursue the action. There, it's -- the Court, I'm  
14 sure, can appreciate, there is a tremendous amount of work  
15 that needs to be done in conducting the discovery in this  
16 case and defending against the discovery in this case.

17 As indicated in -- you know, briefly in the  
18 submission, we have a designated sense of what we think each  
19 of these lawyers will bring to the team. And like any  
20 approach to anything, whether it's a -- whether it's an  
21 athletic competition or a lawsuit or some commercial  
22 project, I mean, there are different roles that are  
23 required. And we feel in order to get to the successful  
24 conclusion or to get to a conclusion, however it may come  
25 out, and we do feel strongly that the people are needed.

1 And your appointment of them helps to both validate that  
2 they are part of the team and also obligate them.

3 Let me address your second question, if I may, as  
4 to costs.

5 I don't -- you know, certainly having additional  
6 members, I -- theoretically it could ask -- add to the costs  
7 that are laid out in advancement of the action, but I think  
8 that would only be in certain circumstances.

9 By way of example, if, for example, every lawyer  
10 showed up here every month when they really didn't need to  
11 be, that would add. And that is why typically we would say  
12 that should not happen. The only lawyers that should show  
13 up in -- are those that were going to have a participatory  
14 role and are lead counsel. And so it's usually limited.

15 Secondly, it -- if depositions have to be taken,  
16 let's say there are 30 depositions that are going to be  
17 taken around the country, someone has to go do them. And so  
18 there will be costs associated with that work whether it's  
19 one lawyer -- or I'm sorry -- five lawyers taking six each  
20 or whether it is, you know, ten lawyers taking three each.  
21 The costs will effectively be identical.

22 And beyond that, the costs -- outlays of costs are  
23 really not increased at all by the addition of team members.

24 I could probably argue that, in fact, without the  
25 team members, the costs could go up.

1           So I do not believe it will materially impact --  
2 really, I don't think it will impact the costs at all.

3           Of course there will be time that is spent on --  
4 by these lawyers. And, you know, we haven't really gotten  
5 to that bridge yet to either cross it or have it blown up,  
6 but we -- there will be some application in the future, I'm  
7 sure, that time spent by lawyers, if we ever get to a  
8 resolution, will be compensated out of a common benefit  
9 fund. Frankly, we haven't even discussed that internally as  
10 to teeing that up.

11           But, yes, there will be additional hours put in by  
12 additional lawyers; but, again, that time has to be spent by  
13 someone. So, you know, I can only do the work of one  
14 person.

15           THE COURT: All that make sense.

16           How is the role on the executive committee going  
17 to be different than, say, the lead counsel, the co-lead  
18 counsel?

19           MR. PENNOCK: Just doing work that we would  
20 otherwise have to pull in lawyers from our own firms to do  
21 the work.

22           So, I mean, work has to be done. And as I said,  
23 you know, I can -- some people around here can probably do  
24 the work of two lawyers. I can do the work of one. And  
25 there's a lot of -- there's a great deal of work that has to

1 be done. So someone has to get on it.

2 If I need three lawyers to take care of one  
3 particular project, they've got to be pulled from somewhere.  
4 And so I would rather that we had senior people dedicated --  
5 and passionately dedicated -- to this case, appointed by  
6 Your Honor, which is an honor. It is a privilege. And  
7 people understand that. And that's why those appointments  
8 are sought.

9 There's no one that has applied for these  
10 positions that sometimes are called out as being people that  
11 just want feathers in their hat. I don't see that in this  
12 slate at all.

13 THE COURT: Yeah. I'm impressed by the  
14 qualifications of the individuals I have reviewed. And my  
15 inquiry is just to the issues of -- is overlap or  
16 duplication and whether all that has been thought through in  
17 a way that makes sense to have an executive committee, a  
18 steering committee, in addition to the other appointments in  
19 the case.

20 MR. PENNOCK: Well, one of the reasons for the  
21 breakdown, Your Honor, is, in fact, to avoid duplication of  
22 effort. So if there is a hierarchy in terms of the  
23 decision-making -- well, the discussion and the  
24 decision-making and the work, then there is in -- we offer  
25 that or suggest that so there is not duplication.



1           In other words, not everyone -- if everyone is  
2 part of one large committee with no designation as to where  
3 they fit, then, presumably, everyone should be sitting at a  
4 table to decide issues. And we know how that can go, right.  
5 The best decisions are made by committees of one, in my  
6 opinion.

7           So we want to break it up in the order that  
8 there's -- there are the decisionmakers, which Your Honor, I  
9 think, has already appointed; but those decisions are being  
10 made with the advice and counsel of other people that are  
11 working on the case, which is the executive committee, and  
12 ultimately the -- you know, any members of the plaintiff's  
13 steering committee.

14           But the idea is that being able to efficiently  
15 move forward, decisions are ultimately made by a smaller  
16 group, counsel to a slightly broader group -- or counsel,  
17 counsel comes from a slightly broader group, and the work  
18 comes from the whole.

19           THE COURT: Thank you.

20           MR. PENNOCK: Thank you, Judge.

21           THE COURT: Any objection from the defense?

22           MR. BEAM: Your Honor, we take no position with  
23 regard to the plaintiff's conclusion.

24           THE COURT: So it appears to me that this has been  
25 a thoughtful process. The individuals who are recommended,

1 I'd actually like to explore their credentials some more,  
2 not because of concern for their merit, because of the  
3 interest in their background. Because it seems to be very  
4 diverse in experience, in a qualified group, so I will  
5 approve the slates as suggested.

6 And I'll just note that already there seems to be  
7 value, in terms of the interaction between the federal cases  
8 and the state court cases. And that, I would assume, would  
9 only be improved upon by -- with a official appointment of a  
10 federal state court liaison. And so the Court will adopt  
11 the slates recommended to it.

12 And then on the other issues that seem to be  
13 agreed upon with respect to the preliminary MDL orders,  
14 proper party orders, agreed waiver service order, agreed  
15 direct filing order; besides that, I will refer later in the  
16 hearing. All of those, the Court is prepared to endorse.

17 And then the agreement with respect to pleadings,  
18 deadlines for amended pleadings, filing counterclaims,  
19 crossclaims and third-party complaints, and the timing and  
20 format of the defendant's answer, all of that seems to be  
21 agreed upon, unless I'm reading this wrong.

22 MR. WRIGHT: Your Honor, I apologize, and you're  
23 reading exactly correctly. I did want to say we had an  
24 almost two-hour conference this morning to talk about a  
25 number of these items that we had not yet reached agreement

1 on, and there were some suggested changes, one of which is  
2 implicated by what the Court just said. If I may report  
3 that, it might be helpful.

4 THE COURT: Yeah, it would be great.

5 MR. WRIGHT: So our colleagues had requested with  
6 respect to the deadline for amended pleadings to extend that  
7 by a period of three-weeks, or until January the 6th. We  
8 agreed to that.

9 That will operate to bump some other deadlines  
10 that are in the agreed -- in the proposal that was submitted  
11 to the Court. Examples being, our deadline for filing  
12 counterclaims would be bumped by three weeks. Our answer --  
13 our generic answer on affirmative defenses are also bumped  
14 three weeks. And our Rule 12 motion would be bumped three  
15 weeks.

16 So, we wanted -- if that is amenable to the Court  
17 and in order to accommodate the plaintiffs on that, that  
18 would be, that would be a suggested change.

19 The other item is not in the order, but I did want  
20 to note for the Court is we had requested an additional week  
21 to respond to their motion to compel. They had agreed to  
22 that. Their reply would obviously be extended, as well.

23 But those are some housekeeping deadlines that if  
24 the Court is willing to accommodate, they're somewhat  
25 different from what's before you. So I wanted to report

1 that.

2 THE COURT: Great. Thank you.

3 If it's agreeable to you all, it's agreeable to  
4 the Court.

5 With respect to whether to allow Rule 12 motions,  
6 there's a difference of opinion on that. It appears to the  
7 Court I have what I need. Does anybody wish to add to that?

8 MR. WRIGHT: Well, I'm pleased to report, although  
9 it's late breaking, that we do have agreement with respect  
10 to that. So, in terms of Merck's proposal with respect to  
11 Rule 12, the plaintiffs are amendable to that. Mr. Pennock  
12 was very quick to disagree with our nomenclature of this  
13 being a bellwether.

14 THE COURT: Bellwether, yeah. What's a better  
15 word for it? I was trying to come up with a better word.

16 MR. PENNOCK: 12(b)(6) motion in two cases.

17 THE COURT: Yeah, that sounds so good.

18 (Laughter.)

19 MR. PENNOCK: But I'm not that creative, Judge.

20 MR. WRIGHT: On that point, the Court will  
21 decide --

22 THE COURT: All right.

23 MR. WRIGHT: -- the prejudicial effect of that.  
24 But other than that, I believe we have agreed to that, as  
25 well.

1           And while we're on a roll, we also agreed with  
2       respect to Merck's proposal with respect to submitting a  
3       generic denial and list of affirmative defenses. There's a  
4       -- that's fully set out.

5           But the one tweak there that we agreed to is they  
6       wanted the right on remand to be able to file an amendment  
7       to deal with state-specific issues as a matter of right, and  
8       we agreed to that.

9           So, with that tweak or change, I believe the  
10      parties, with respect to the Rule 12 and the answer, they  
11      are aligned. And if the Court is amenable to that, there  
12      would be no further decision from the Court required on  
13      those issues.

14           THE COURT: All right.

15           Thank you.

16           MS. GIESER: And, Your Honor, if I may. And there  
17      are other agreements that we reached this morning, too. A  
18      number of matters that will probably come up as the Court  
19      brings them up.

20           And the airlines should know that the -- there --  
21      that Zoom has not completely displaced them because the  
22      in-person meeting that Mr. Wright suggested this morning was  
23      immensely helpful. In person really works. We were  
24      grateful that he got up early and met us at the office.

25           THE COURT: Yeah, there's just something that

1 happens when people meet in person that doesn't happen as  
2 often when you're sitting behind the keyboard. And I don't  
3 know. It's an interesting phenomenon, but I appreciate the  
4 effort.

5 This is an adversarial system, and we're going  
6 to -- y'all are going to fight over various things. But  
7 what seems to be coming out of this case -- and it's kind of  
8 juxtaposed to some other experiences I've had recently where  
9 that wasn't the case -- it does appear to be a winnowing and  
10 a narrowing of things so that the effort is expended on the  
11 things that matter, and I appreciate that from all counsel.

12 All right. I think I have what I need on that.

13 Do y'all wish to be heard on the areas of  
14 disagreement on the FAQ sheets, mental health records and  
15 social media things? Or do you believe I have what I need  
16 to make decisions in that area?

17 MS. JULIEN: Your Honor, we're happy to be heard.  
18 But, you know, if you believe that you have what you need,  
19 we're happy to defer to that, as well.

20 THE COURT: I think I have what I need. But if  
21 there's a need to hear more, I'm open to that, too.

22 MS. JULIEN: Yes, Your Honor.

23 I think maybe one area that's perhaps worth  
24 clarifying is with respect to the vaccine court file. Just  
25 really wanted to, to hit home the, the lack of burden here.

1           We had an agreement in place with Mr. Esfandiari's  
2 firm for more than a year whereby the plaintiff would sign  
3 an authorization form, provide a scanned copy of his or her  
4 ID, and that was submitted to the vaccine court clerk, and  
5 the materials were collected in that manner. So we really  
6 just don't believe that, that there's, you know, any real  
7 burden to be had here and think that that status quo system  
8 should remain.

9           THE COURT: Anybody want to respond to that?

10           MS. MULLINS: Yes, Your Honor. Actually, I'm glad  
11 Ms. Julien brought this up because I do think it's an  
12 important issue for the Court to consider, and particularly  
13 the differences between the vaccine program and what we do  
14 here in Federal Court.

15           For one thing, the presumption is exactly the  
16 opposite. And here in this court, everything is presumed to  
17 be open unless Your Honor puts something under seal for some  
18 reason.

19           The direct opposite is true in the vaccine  
20 program. And, in fact, those records, by -- even under the  
21 Federal Register, are not public record. And it is very  
22 limited what -- who can access those.

23           So to say that there is no burden, first of all,  
24 is just factually incorrect. It is not possible for us to  
25 give a release -- first of all, it's not appropriate, but

1 it's also not possible. They've agreed that they should not  
2 receive attorney billing records, which have to be submitted  
3 in the vaccine program.

4 And so already we -- there are things that are  
5 carved out that can -- that by agreement should not be  
6 received.

7 THE COURT: It is my understanding that you have a  
8 third-party vendor that, that screens in, in terms of  
9 production of these?

10 MS. MULLINS: No.

11 THE COURT: Am I wrong about that?

12 MS. MULLINS: No, not for these materials.

13 The initial problem is that for that release to go  
14 forward, first of all, the Government would have to agree to  
15 have all of those files released.

16 Second, now you're asking the clerk's office in  
17 the vaccine program to only provide certain information. So  
18 that's just -- that's not possible.

19 What will happen, instead, is that the lawyer who  
20 represented that petitioner in the vaccine program would  
21 have to go through these materials. There's literally one  
22 lawyer that can do that. Even if multiple lawyers have  
23 entered an appearance, only one lawyer can enter -- can  
24 access those materials.

25 And so it is a very significant burden.



1 But more fundamentally, it's very clear under the  
2 case law that these materials are not admissible for any  
3 purpose in this court, other than to show that the  
4 requirements were met of the prerequisite of filing in the  
5 program.

6 And we have Mr. Downing here, who his primary  
7 practice is in the vaccine program, and that's why we have  
8 him. I'd like, with your Honor's permission, to have him  
9 give the Court some orientation to, to just how this program  
10 operates and how it's different fundamentally from federal  
11 court and from general discovery.

12 THE COURT: I'd be glad to hear from Mr. Downing.  
13 But let me ask you first.

14 What has changed since the summer of '21 and now  
15 in terms of your posture with respect to these records?

16 MS. MULLINS: Well, Your Honor, frankly -- and  
17 Mr. Esfandiari would have to address that, but the defense  
18 has talked a lot about starting afresh with respect to this  
19 court and aligning everything in the MDL.

20 This happened with respect to litigation that was  
21 happening pre-MDL, some in California and, frankly, by folks  
22 who don't regularly practice in the vaccine program and did  
23 not necessarily appreciate the differences and distinctions  
24 in that program and why those materials should not just be  
25 ported over.

1           And so that's -- it's not necessarily a change in  
2 terms of -- well, I think that once we started the MDL, we  
3 had people who do operate within the vaccine program and  
4 could say "Look, there's all sorts of stuff in this, that  
5 goes forth here that should not just be ported over. It  
6 shouldn't be some sort of automatic thing. It's not -- it's  
7 just not an appropriate use of the program materials."

8           What we would say, Your Honor, is there are two  
9 things that would be -- two inquiries. The first is: Is  
10 the document necessary to show that the requirement has been  
11 satisfied? That's limited to two or three documents  
12 depending upon how the case exited the program, the  
13 petition, the resolution at the court; and if it was  
14 resolved by a dismissal or by a judgment, then the rejection  
15 of that and the election to come to civil court.

16           So those three things are relevant.

17           Beyond that, the question should be not whether it  
18 was filed in the vaccine court or whether it was submitted  
19 in that program but, rather, whether it's independently  
20 discoverable.

21           So if we get into a case with full discovery,  
22 certainly if there's prior sworn statements, for instance,  
23 by a witness or by the plaintiff, those are going to be  
24 discoverable independent of where they were filed. And so  
25 that would be appropriate to come over into this court. But

1 -- and into discovery.

2 But beyond that, it's just -- it's, it's -- we  
3 have started de novo. The Supreme Court says that nothing  
4 that happened -- this is a de novo consideration of the  
5 case. The case law is replete saying that nothing, no  
6 finding, no conclusion, nothing that happened in the vaccine  
7 court has any bearing whatsoever on what happens in this  
8 court.

9 We are also multiplying issues just by porting  
10 that over, in addition to the burdensome nature of it.

11 For instance, if you have expert reports, those  
12 people may be consulting experts here; they may not be  
13 testifying experts. And in that case, those materials would  
14 be protected under federal rules of civil procedure; they  
15 wouldn't be automatically disclosed.

16 On the other hand, if it is an expert that comes  
17 forth into this case, the specific -- was in the vaccine  
18 program for that plaintiff, is in this case for that  
19 plaintiff -- then those materials may be properly  
20 discoverable.

21 But it's not because they were in the vaccine  
22 program; it's because they're independently discoverable for  
23 a different reason.

24 And so I think that by trying to create some  
25 blanket provision, we multiply unnecessary issues for

1 materials that the courts have been very clear are not  
2 admissible, are not -- have no bearing on the proceedings  
3 here.

4 MS. JULIEN: Your Honor, may I please briefly  
5 respond before Mr. Downing speaks? There were -- there was  
6 quite a bit to cover.

7 THE COURT: When you're not talking, feel free to  
8 sit down.

9 MS. JULIEN: Okay. So quite a bit was covered  
10 there. But I think to get back to the centerpiece here,  
11 Merck is entitled to plaintiff's entire vaccine court file  
12 with the exception of the attorney billing records and not  
13 the bits and pieces selected by plaintiff's counsel.

14 There -- these files are directly relevant and  
15 are -- provide a wealth of probative information about the,  
16 the facts at issue here.

17 You Honor, honestly, as I sit here, I struggle to  
18 think of a more directly relevant piece of information.  
19 These files are a prerequisite legal proceeding regarding  
20 the exact same plaintiffs in this MDL who were ostensibly  
21 trying to establish that the exact same vaccine at issue in  
22 this MDL, Gardasil, supposedly caused the exact same  
23 injuries at issue that they -- you know, they claim here in  
24 the MDL.

25 Ms. Mullins repeatedly referred to a statutory

1 provision regarding the admissibility of the findings of  
2 fact or the conclusion of law of the vaccine court, but  
3 that's a far cry from relevance and the question of  
4 discoverability. Rule 26(b)(1) makes clear that they are  
5 not one and the same.

6 But beyond the conclusions of law reached by the  
7 vaccine court or the factual findings, these materials are  
8 full of information that are directly relevant to Merck's  
9 defenses, including timeliness, exhaustion, and implied  
10 pre-emption with -- which we previewed for the Court in our  
11 position statement.

12 Beyond that, the materials in the file are  
13 relevant to the plaintiff's credibility. If he or she made  
14 one statement or alleged one thing in vaccine court and then  
15 come before Your Honor and alleging something different,  
16 that is relevant. And we are able to cross-examine and  
17 consider that as we select bellwether cases.

18 THE COURT: Well, I think as I understand the  
19 plaintiff's position, it's -- various records may indeed be  
20 relevant, but their discoverability is based upon the  
21 relevance and not the fact that they're part of a record.

22 MS. JULIEN: Yes, Your Honor. And I -- you know,  
23 if the Court -- if it would be useful to the Court, we're  
24 able to more fully brief this issue.

25 But to use one example of pre-emption, in vaccine

1 court, again, the plaintiffs were attempting to show that  
2 Gardasil caused the injuries that they are supposedly  
3 claiming in the MDL now. And in vaccine court, the  
4 Department of Health and Human Services is the Respondent.  
5 And the Department of Health and Human Services is the  
6 parent agency of the FDA.

7           So all of the information that HHS considered and  
8 received from the plaintiff, whether that's medical  
9 literature, whether that's the opinions of their expert --  
10 of their experts, whether that's the, the facts in the case,  
11 all of that information is relevant to what the FDA knew at  
12 the time of the use of plaintiff's -- plaintiff's use of the  
13 Gardasil vaccine and whether -- and the question of whether  
14 their claims are preemptive.

15           So if HHS, and thereby FDA, knew of all the facts,  
16 knew the medical literature, considered that, offered  
17 reports explaining why that didn't suffice, that is relevant  
18 to Merck's implied pre-emption claim.

19           Additionally, Ms. Mullins referred to consulting  
20 experts in this MDL who provided written opinions in vaccine  
21 court and exchanged those with the Federal Government and  
22 provided that to a special master.

23           I'm not quite sure -- I'm not aware of a privilege  
24 where a written report has actually been provided to the  
25 Federal Government and to the special master, again, in

1 order to try to establish that the plaintiff -- that  
2 Gardasil caused the plaintiff's alleged injury.

3 One other issue that I wanted to clarify was with  
4 respect to how Merck's -- how the process would work if the  
5 Court adopted Merck's proposal.

6 So we do have a vendor who can work through these  
7 files and can redact or remove materials that they're  
8 privileged attorney billing records. They've actually done  
9 that in the eight vaccine court files that we've already  
10 received from plaintiff's counsel, and they can continue to  
11 do that.

12 And another option is to -- the vaccine court  
13 file, even though the submissions are sealed, we can see the  
14 docket entry, so we could tell the clerk: We want the  
15 vaccine court file, but please exclude Docket Number 42 or  
16 45. So that's a lot simpler than the plaintiff's proposal,  
17 which will require them to wade through potentially  
18 thousands of pages of vaccine court files and pick and  
19 choose which portions they're going to provide to Merck and  
20 when.

21 And one other issue to clarify is -- I know this  
22 is covering a lot here, but she raised a lot -- is with  
23 respect to what happened before. And I'm not aware of  
24 anything that has, that has actually changed because  
25 Mr. Downing is counsel of record in Gramza (ph), which was

1 the first case in which we got the vaccine court file. And  
2 we took this issue to the court, it was resolved.

3 Mr. Esfandiari had agreed to give us the vaccine  
4 court file, the authorization and the file from Mr. Downing.  
5 And so, you know, he was involved. There was no objection  
6 there about appropriateness or relevance at that time, so  
7 I'm a bit confused as to what has changed.

8 So, again, Merck just requests that the status quo  
9 remain that we receive the expert reports. They're  
10 relevant. They're, cross examination information. They're  
11 important to potentially lead to other discoverable  
12 information. And that -- really, it just provides a wealth  
13 of information. And plaintiffs have not identified any  
14 basis to include the actual underlying materials.

15 We're not talking about the conclusion of law or  
16 the finding of fact of the court here.

17 THE COURT: Mr. Downing, your name's been taken in  
18 vain a few times. I'll be glad to hear from you.

19 MR. DOWNING: It has, Your Honor. And this is my  
20 first time addressing you in this case. I appreciate the  
21 opportunity.

22 THE COURT: Yeah, well --

23 MR. DOWNING: Your Honor, just a few things. And  
24 Ms. Mullins, I think, covered a lot of what I was intending  
25 on explaining in terms of how the vaccine program works.



1           But I think it bears noting: The vaccine program  
2 is not a court. It's been called the "vaccine court." It's  
3 not. It's an administrative program run by Health and Human  
4 Services. The standards are completely different than they  
5 are here. It's a sealed process. The only people that have  
6 access to anything is one counsel of record for the  
7 plaintiff or the petitioner, one counsel of record for the  
8 Government, which is the DOJ, and the Court. That's it.  
9 The public's not allowed to attend a hearing. There is  
10 nothing public in those cases.

11           And so in addition to just a sealed process, the  
12 way the program operates is different. The standards are  
13 different. There's no discovery. The evidentiary standards  
14 are completely different. What you're trying to prove in  
15 the vaccine program is completely different and the way you  
16 go about it is different than what will be done in this  
17 case. Experts may be different. And likely will be.

18           What you end up having here -- and I've tried to  
19 make some notes as counsel was addressing them.

20           For example, the concern Merck has as far as the  
21 FDA's involvement and what they knew and the evidence  
22 presented in terms of that, that's not done in the vaccine  
23 program. It's a no-fault system. The only question that  
24 ever gets put to the special master in a vaccine case is:  
25 Did you receive the vaccine at issue and were you harmed?

1 That's it. And if you were harmed, you're afforded damages.

2 None of what Merck is trying to get at through  
3 pre-emption or any of the other issues that counsel brought  
4 up are even at issue in the vaccine program.

5 Ms. Mullins indicated to Your Honor that the  
6 process here is de novo. That's -- I mean, that's  
7 important. It's a start-over. Were -- you know, these  
8 plaintiffs are not bound by what they said in the vaccine  
9 program. It's not relevant. It's not admissible. It's not  
10 impeachable evidence.

11 Now, when you get into, as both counsel, I think,  
12 said, when you get into the bellwether cases and whatever  
13 discovery plan Your Honor wants to adopt, those are  
14 discovery issues for this court to supervise. You shouldn't  
15 simply release a sealed file in every single case where it's  
16 not warranted.

17 I think that we cited in our paper that Yale (ph.)  
18 versus Aventis case, which was an Eastern District of  
19 Louisiana case, that case clearly said that the vaccine  
20 proceedings serve really one purpose in a civil filed case  
21 that comes later, and that is: Did the plaintiff comply  
22 with the prerequisites to appear in this court? Did they  
23 file in the vaccine program? And did they get out?

24 So, in these cases, you can give them the  
25 petition, which reflects filing. And you can get the

1 concluding document, which shows that they exited. That  
2 demonstrates that these plaintiffs satisfied the  
3 prerequisites to appear before Your Honor in this case. And  
4 that is the extent of the relevance, the usefulness, and  
5 then I think the discoverability of the entire vaccine file.

6 I can go on and on about the vaccine program.

7 THE COURT: No.

8 MR. DOWNING: I think you've got a grasp on that,  
9 and I think Ms. Mullins did a good job of describing it.  
10 I'll -- I'd be happy to answer any questions that you've got  
11 there.

12 THE COURT: Thank you.

13 MS. JULIEN: Your Honor, very briefly, I know  
14 we've covered this quite a bit, but I think Mr. Downing  
15 really drove home a point of the information asymmetry  
16 created by the plaintiff's proposal. So I think the sheer  
17 fact that he's sitting at the table with co-lead plaintiff's  
18 counsel in this MDL makes clear that they have access to the  
19 entire vaccine court file. Their experts, the lawyers here  
20 can access that.

21 Mr. Downing, again, provided the vaccine court  
22 file that he had in his possession, at least the plaintiff's  
23 portion of it, without issue in Gramza. And, again, we've  
24 had this proposal in place for more than a year where none  
25 of these --

1 THE COURT: You're starting to repeat.

2 MS. JULIEN: Yes, apologies.

3 And the -- and, lastly, just to clarify with the  
4 EO opinion pointed out by Mr. Downing, to be clear, that  
5 court did not hold or even suggest that the only potential  
6 use of the vaccine court proceeding is a confirmation or  
7 box-checking confirmation that a particular plaintiff  
8 complied with the statutory prerequisites before filing the  
9 lawsuit; the Court merely repeated what is the statutory  
10 provision Section 300aa-23(e), which we don't dispute. That  
11 is that the findings of fact and that the conclusions of law  
12 are not admissible.

13 But that doesn't speak to the discoverability of  
14 the file itself. In fact, none of their -- none of the  
15 cases that they cite support their position there.

16 Thank you.

17 THE COURT: Yeah. And the other two issues are --  
18 I'm going take all this under advisement -- the other two  
19 issues are the mental health records and the social media  
20 and photo/video information sought and objected to.

21 Again, I have what I think I need, but if anybody  
22 wants to be heard on that, I'd be glad to hear from you.

23 MR. PENNOCK: We're okay. Thank you, Judge.

24 THE COURT: Thank you.

25 MS. JULIEN: We are, as well. Thank you.

1           THE COURT: So now on the discovery plan, you  
2 know, it seems to be a fork in the road type of thing. I'm  
3 very -- I see benefits in taking each road in terms of time  
4 to destination with respect to the plaintiff's plan and then  
5 an earlier assessment of value of the case from both sides  
6 with respect to the defendant's proposed phased plan.

7           I intend to pick and proceed, but I'll be glad to  
8 hear from either side if you think that I need to consider  
9 something other than what you've already proposed to me.

10          MR. DUKES: Your Honor, just one additional issue.  
11 It's -- as a tangible example of the benefit of efficiency  
12 with regard to our proposal, just last week in the Zantac  
13 MDL, Ms. Rosenberg, down in the Southern District of  
14 Florida, had structured that MDL, which my firm and others  
15 participated in so that general causation was the Phase 1  
16 decision, and last week in a 341-page opinion, she ruled in  
17 favor of the defendants and dismissed all of the cases on  
18 that docket as a result of the decision on general  
19 causation.

20          So I think the parties have thoroughly briefed it.  
21 I did just want to provide a tangible recent example of why  
22 this process can be so efficient.

23          THE COURT: I hope there was a summary of opinion  
24 in that case.

25          (Laughter.)

1 MR. DUKES: Your Honor, we have one other  
2 agreement. We got several other agreements. And it was a  
3 good morning.

4 We have agreed to the alleged injuries that would  
5 be pursued in discovery under either -- of either proposal.  
6 Potts was one that we had proposed that's agreed to.

7 Plaintiffs this morning proposed primary ovarian  
8 failure, and Merck has agreed to that.

9 So we now have agreement on which alleged injuries  
10 would be pursued from a discovery standpoint.

11 THE COURT: Would it be helpful, do you all  
12 believe, to file an amended report that reflects some of the  
13 good work that's been accomplished today?

14 MR. WRIGHT: And we actually discussed that. And  
15 certainly, also, we'd be willing, although it's a bit  
16 unusual to draft the entire proposed order for the benefit  
17 of the Court, there are some nuances here. We may be better  
18 situated to reflect that and present it.

19 So we can certainly -- I would suggest maybe doing  
20 that as opposed to sort of an amendment of all of this.

21 THE COURT: It makes sense to me, Mr. Pennock.  
22 What do you --

23 MR. PENNOCK: Yes, Your Honor. That's --

24 THE COURT: Yeah, the joint proposed order would  
25 be embraced by the Court, --

1 (Laughter.)

2 -- provided it was timely submitted.

3 MR. PENNOCK: All right.

4 Your Honor, as to the, you know, truncated versus  
5 traditional approach, I would just like to add to what has  
6 been said in our -- briefly in our papers. That from our  
7 vantage point, although the efficiencies of approaching it  
8 our way, we think, are superior in that we will create cases  
9 ready for trial should we prevail rather than have to move  
10 on as we laid out.

11 But the -- I think there's also a substantive  
12 component to our position that I don't want to be lost in  
13 the efficiency discussion, and that is that whether or not a  
14 part -- this particular compound, the vaccine, caused injury  
15 in particular people is something that we would be  
16 evaluating and would necessarily have to be evaluated.

17 And so I think that it would be an overstatement  
18 for me to say that pursuing just general causation were in a  
19 vacuum. But it's not a -- it's not completely inaccurate.  
20 Pursuing a case, the fulsome case, of people who are  
21 claiming to have been injured by this vaccine with the  
22 constellation of evidence that supports that claim,  
23 generally as well as specifically, is not only the way that  
24 I think we are all accustomed to proceeding with trying to  
25 prove what has happened to someone, but I think that is the

1 best way to get at the root of all of the questions here.

2 THE COURT: So, in then -- in a "can it, did it"  
3 continuum, why can't I take one of those in isolation and  
4 deal with it and then have the parties in a better position  
5 to deal with the specific causation?

6 MR. PENNOCK: Well, I think the Court could take,  
7 as the court did in the Zantac case, could take -- which, by  
8 the way, maybe I should add, I declined being involved in  
9 that case because I thought that the general causation was  
10 very weak in that case -- but the Court could take it as a  
11 general causation only.

12 But what we are doing inevitably or under both  
13 proposals, we are doing case-specific discovery. We are  
14 getting at the plaintiff. We are getting at the  
15 plaintiff's, the plaintiff's doctors. All of that is  
16 happening.

17 And yet, then we're just going to put -- pull the  
18 emergency brake and not proceed to issue expert reports  
19 case-specific -- who by the way, I want to make clear, the  
20 case-specific opinions are predicated not upon someone  
21 else's general opinion but upon their own general opinion.  
22 In a case such as this or any toxic exposure case or  
23 pharmaceutical exposure case, the case-specific expert needs  
24 to and does evaluate all of the general evidence, evaluates  
25 it and comes to the conclusion, if he or she does, that the



1 vaccine is capable of producing the injury claimed.

2 Then that expert takes that view and applies it to  
3 an individual case and makes a determination and offers an  
4 opinion as to whether or not it happened in that individual  
5 case.

6 And, I mean, I'm -- I can tell you quite  
7 transparently that there are cases that I've handled many  
8 times where the -- where that expert says, "I'm sorry. I  
9 can't offer that opinion in this case." And the case is  
10 dismissed, as the defendants have raised previously.  
11 They're concerned about the bellwether pool being reduced by  
12 such dismissals.

13 So the process will simply work to evaluate each  
14 and every aspect of what happened medically with what will  
15 be hundreds of people are claiming in this matter.

16 And so, again, I repeat myself, but substantively,  
17 I think this is a better process, not just efficiency-wise.

18 THE COURT: Thank you.

19 All right. Y'all don't need to write that part of  
20 the --

21 (Laughter.)

22 -- report.

23 How long do you all need to file your proposed  
24 order?

25 MR. WRIGHT: Say, January 6th?

1 MR. PENNOCK: That's fine.

2 THE COURT: All right. And then I'd like to set  
3 another meeting because this calendar fills up really  
4 quickly these days. I think it's really helpful for the  
5 Court -- and you've demonstrated that it's helpful for you  
6 all -- to have a -- a hearing-related reason to get  
7 together.

8 And so I'd like to set a, I'd like to set a  
9 "science day." It's a -- but you all -- I'm convinced by  
10 myself that I'm an ocean of ignorance in terms of science.  
11 And I'm convinced by you all that it would be helpful to get  
12 this tutorial in place. And so I'd like to do it. And it  
13 seems to me the sooner in the process, the better.

14 And I thought it might be an efficient use of time  
15 if we combine that with a next hearing date. And if that's  
16 amenable to both sides, I'm suggesting the last week of the  
17 month of January 30th.

18 MR. DUKES: Your Honor, that's amenable for Merck.

19 MR. WRIGHT: And I believe we actually talked  
20 about February 3rd as a science day, which was amenable to  
21 the parties, as well.

22 THE COURT: So a day earlier in that week?

23 MR. WRIGHT: Fine from our standpoint.

24 MR. PENNOCK: Judge, sorry. I'm trying to pull  
25 up. A date earlier in that week would --

1 THE COURT: February 2nd?

2 MR. PENNOCK: -- I think they had a conflict on  
3 that date.

4 THE COURT: They do?

5 MS. JULIEN: Yes, Your Honor, I apologize. I  
6 believe one of my colleagues, who would likely be present  
7 here, has a conflict on that day, on February 2nd. I don't  
8 know if the 30th might work for plaintiff's counsel?

9 MR. PENNOCK: Sure.

10 THE COURT: So any other day that week --

11 MR. PENNOCK: Is good.

12 THE COURT: -- is good with the Court.

13 So is the 31st a good day?

14 MR. PENNOCK: Yes, Your Honor.

15 MS. JULIEN: Yes, Your Honor.

16 THE COURT: Let's do that, then. Tuesday the 31st  
17 we'll have a hearing and a science day scheduled for that.

18 MR. DUKES: Your Honor, we, over the course of  
19 negotiations, had several disagreements regarding the exact  
20 issues -- not issues, but some of the logistics of science  
21 day. We resolved those this morning, so we'll be prepared  
22 to submit --

23 THE COURT: With a lot of the people in this  
24 room --

25 (Laughter.)

1           -- the balance of the day, let's see where we  
2 stand at the end.

3           All right. Well, good. I'll be interested in a  
4 proposal on that, too.

5           MR. DUKES: Yes, Your Honor.

6           MR. WRIGHT: One aspect of that, just I'll mention  
7 because it's an institutional concern for you, is that  
8 there's general agreement on our side that this will be a  
9 closed proceeding with respect to science day. I did want  
10 to mention that that -- obviously, counsel of record could  
11 be here, but that would be our proposal.

12          THE COURT: Sure. And I don't know that we even  
13 need to have it on record unless either side requested it.

14          The hearing will be transcribed and official, but  
15 the science day portion of it will be closed and unofficial.

16          All right. Anything else we need to discuss this  
17 morning?

18          MR. WRIGHT: Your Honor, I would say one other  
19 item that would be helpful to us, if the Court is able to do  
20 it, is as we think about status conferences in advance in  
21 terms of planning, if there are dates, looking forward, that  
22 are open on the Court's calendar that we could at least  
23 pencil in subject to change, that would be, also, well  
24 received.

25          THE COURT: Is monthly too frequent at this point?

1 MR. PENNOCK: No.

2 THE COURT: So what if we, what if we calendared  
3 in, subject to conflict, the last Tuesday of every month?

4 MR. PENNOCK: That would be great, Judge.

5 MR. WRIGHT: Thank you.

6 THE COURT: That works for me because the way we  
7 do things around here, the criminal and civil trial terms  
8 begin the first Monday of every month. And so usually by  
9 that last week, all of that trial work is resolved. If that  
10 changes, I would be, I would be very pleased with that.  
11 That would mean we're having more trials than we're having  
12 now.

13 But, well, at the rate we're going, that last week  
14 of the month is pretty open for us. So we'll tentatively  
15 calendar in a pretrial conference the last Tuesday of every  
16 month at -- is 11 o'clock a good time for you all?

17 MR. PENNOCK: Yes.

18 THE COURT: All right. Well, good. I look  
19 forward to proceeding from this point. I'll -- I will get  
20 out -- I'll receive your proposed order and respond to it  
21 quickly and get it out to you so we're making use of our  
22 next conference at the end of January effectively.

23 Thank you, all of you.

24 (Court recessed at 11:51 a.m.)  
25

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NORTH CAROLINA

CERTIFICATE OF OFFICIAL REPORTER

I, Kathy Cortopassi, RDR, CRR, CRC, Federal Official Court Reporter, in and for the United States District Court for the Western District of North Carolina, do hereby certify that pursuant to Section 753, Title 28, United States Code, that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Dated this the 21st day of December, 2022.

/s/ Kathy Cortopassi  
Kathy Cortopassi, RDR, CRR, CRC  
U.S. Official Court Reporter